K033722

MAY - 7 2004

510(k) Summary

Submitter:

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University of London
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E1 4NS

Contact Person:

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Date Prepared:

November 19th, 2003

Classification:

Resorbable calcium salt bone void filler devices have been classified by the Orthopedics Device Panel as Class II Special Controls per 21 CFR 888.3045

Trade Name:

ApaPore® Bone Graft Substitute

Common Name:

Synthetic, porous hydroxylapatite

Predicate Devices:

Isotis NV OsSatura™ BCP Bone Void Filler
Isotis S.A.
K030131 – cleared May 20, 2003

Intended use:

ApaPore® is a bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure. ApaPore® is indicated to be packed gently into bony voids or gaps of the skeletal system, i.e. extremities, spine and pelvis. These defects may be surgically created osseous defect or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Device Description:

ApaPore® is phase-pure hydroxylapatite osteoconductive bone void filler, comprising a single-phase calcium hydroxylapatite scaffold. The interconnected and open porous structure of ApaPore® is similar to human cancellous bone. ApaPore® is available as irregularly shaped chips of 2 different sizes, in a choice of 3 porosities to suit surgeon preference.

Technological Characteristics and Substantial Equivalence

ApaPore® is composed of a porous calcium salt, hydroxylapatite, equivalent to that contained in both predicate devices and to that in routine clinical use. The technologies employed in ApaPore® and both of its predicate devices is therefore substantially equivalent. ApaPore® is presented in irregular granules or chips in the same manner as its predicate devices. Its indications, contraindications, risks and potential adverse events are the same and thus substantial equivalence is claimed for the device.

Testing

Extensive bench testing has shown ApaPore® to meet the requirements of all relevant standards for Calcium Salt Bone Void Fillers. Extensive preclinical testing has confirmed ApaPore® to be safe and effective in providing a scaffold for rapid bone repair via bony infiltration of the porous scaffolds. ApaPore® has been regularly used clinically for the past 16 months and no adverse events have been reported.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2004

Apatech Ltd.
C/o Barry Sall, RAC
Senior Regulatory Consultant
Parexel
195 West Street
Waltham, Massachusetts 02451-1163

Re: K033722
Trade/Device Name: ApaPore® Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler
Regulatory Class: II
Product Code: MQV
Dated: April 2, 2004
Received: April 2, 2004

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

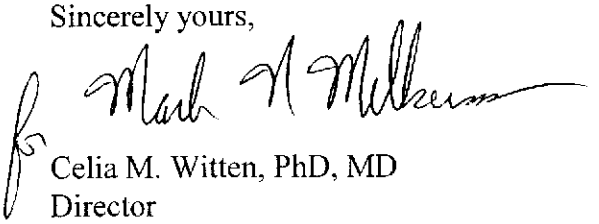
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, PhD, MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033722

Device Name: ApaPore® Bone Graft Substitute

Indications for Use:

ApaPore® is used in open bone voids that may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. ApaPore® is intended for use on bone voids/gaps that are not intrinsic to the stability of the bony structure of the skeletal system, i.e., in the extremities, spine and pelvis.

ApaPore® is intended to be carefully packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine or pelvis). Following placement in the bony void, the synthetic bone void filler ApaPore® provides a scaffold for new mature host bone growth.

Prescription Use___X___ (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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